



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

AA
#17
4/25/02

IN RE APPLICATION OF: Nora B. Aghassi, et al.	ATTY DKT NO. P-6335.01(CIP)
SERIAL NO. 09/515,283	Group Art Unit: 1641
FILED: February 29, 2000	Examiner: Grun, James Leslie
TITLE: COMPOSITION AND METHOD FOR TREATING TISSUE SAMPLES	RECEIVED
TO: Assistant Commissioner for Patents Washington, D.C. 20231	APR 24 2002 TECH CENTER 1600/2900

DECLARATION OF DR. MIKE LACEY UNDER 37 C.F.R. § 1.132

I, **MIKE LACEY, M.D.**, declare as follows:

I Have been involved in the Practice of Pathology for 20 years and have focused exclusively on the specialty area of Immunohistochemistry for the past 3 years as an associate of Cell Marque Corporation. I have the following comments with regard to the Declere/Trilogy (Cell Marque) method of slide preparation prior to the actual staining procedure when immunohistochemical methods are employed:

1. The Declere/Trilogy method as currently claimed is the most rapid and effective fixed tissue method preparation method for immunological staining.
2. The Declere/Trilogy method as claimed in U.S. Serial No. 09/515,283 induces the most effective epitope retrieval and therefore staining for most antibodies as compared to other methods to which I have had exposure (approximately 115).
3. There is adequate deparaffinization, rehydration, and unmasking of the tissues during this process such that immunostaining can proceed.
4. To my knowledge these were the first products on the market which accomplish the three step process (deparaffinization, rehydration, unmasking) with one solution.
5. The 1997 application (U.S. 08/957,098), in my view, clearly provides a description enabling one of skill in the art to perform the claimed invention. (as mentioned in the accompanying response to Office Action) For example, see pages 4, 13 and 15-17.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Mike Lacey M.D.
Mike Lacey, M.D.

Date: 4-15-02

EXHIBIT "A"

DATE

pH meter range check

Calibrated 6 NOV 95 ~ 11 PM for pH 7-10 - no further calib.

Fresh aliquots of std pH 4, 7 & 10 buffers prepared (N)

Old aliquots also tested (old

pH

	Std 4.00	7.00	10.00
Old	3.78	6.94	10.00
New	3.78	6.96	10.05

If pH meter has not ^{last} been calibrated for the range needed, it should be calibrated for the correct range before use.

DATE

Pretreatment

Deparaffinization: Xylene ^{no heat}, Xylene Sub. ^{no heat}

Rehydration: Alcohols ^{no heat}

Unmasking: Citrate buffer (Citric Acid, Hcl, DTG) + heat

DATE

One step pretreatment with citrate buffer plus emulsifier to deparaffinize in aqueous solution to rehydrate

DATE

Emulsifiers: Tween 20, Brij 55, Gue gone, Sim Citrate buffer + Simple Green in PC: Vm: 4+/1 L 26 4+/1. CK AEI/3 4+/1 ☺ - Nov 95